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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,629	01/29/2004	Karla Weaver	10123/00901	6763

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EXAMINER

WACHTEL, EMILY L

ART UNIT	PAPER NUMBER
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3709

MAIL DATE	DELIVERY MODE
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10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,629

Applicant(s)

WEAVER ET AL.

Examiner

Emily Wachtel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :June 13, 2005, November 13, 2006, and January 11, 2007.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a pressure activated valve classified in class 604 subclass 247.
 - II. Claims 8-15 drawn to a method of making a membrane for a pressure activated valve classified in class 604 subclass 537.
 - III. Claims 16-28 drawn to a flow control device for a pressure activated valve classified in class 604 subclass 247.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the pressure activated valve in claim 1 of Group I does not require the particulars of the flow control membrane in claim 16 of Group III such as it does not require a base membrane which overlies a seating portion of a membrane. The subcombination has separate utility such as a control device for use in a non-medical application as required in claim 1, for example in a water bottle.

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The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as forming a single layered membrane (i.e. without using an annular base membrane).

4. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as forming a membrane having a central cut portion in the form of a flap which pivots (or flaps) about the line connecting opposite ends of the line cut to form the flap. Opening when it experiences a pressure and otherwise remaining closed.

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5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be

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considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Patrick Fay on September 14, 2007 a provisional election was made without traverse to prosecute the invention of the pressure activated valve claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-28 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. The abstract of the disclosure is objected to because it exceeds a length of 150 words.

Correction is required. See MPEP § 608.01(b).

10. The disclosure is objected to because of the following informalities:

Page 2 [0001] Amended specification paragraph repeats the reference of application

10/768,571. I believe the reference to the Pressure Activated Safety Valve With High

Flow Slit has been omitted. Please omit and replace the repeated reference as necessary.

Page 3 [0008] insert --a-- between --is diagram--

Page 8 [0016] insert --ed-- to the end of --extend--

Page 9 [0018] --if-- should be inserted in the place of --iff--

Page 10 [0020] --This-- should be inserted in place of --Ths--

Page 12 [0024] --t1 and t2-- should be inserted in place of --b1 and b2--

Page 14 [0028] --with-- should be inserted in place of --that-- in the phrase --periphery that dimensions that--

Page 14 [0028] --described-- should be inserted in place of --descried--

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Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorehead et al. (U.S. Patent 5,205,834).

With regards to claim 1, Moorehead et al. teaches a pressure activated slit for medical applications (Col. 2 line 10) comprising a housing having a lumen extending therethrough from a proximal end to a distal end (Fig. 2 element 42), a flow control membrane (Fig. 5 elements 120, 124) including a mounting portion at which the flow control membrane is coupled to the housing (Fig. 5 element 120, Col. 6 lines 1-5) and a lumen occluding portion having a slit (Fig. 5 element 124, 146) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Col. 2 lines 29-32) and wherein a thickness of the mounting portion is greater than a thickness of the lumen occluding portion (Fig. 5 elements 120, 124, Col. 7 lines 17-20 base members add thickness to mounting portion and not to the area encompassing the slit).

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With regards to claim 3, Moorehead et al. teaches a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 5 elements 90, 120, 124, Col. 6 lines 47-53).

Additionally, the outer periphery of the membrane (Fig. 5 elements 120, 130) is contiguous with the housing (Fig. 5 element 90). Therefore, the housing is applying a compressive retentive force on the membrane, as the membrane is secured within the housing and not free to move.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) as applied to claim 1 above.

With regard to claim 2, Moorehead et al. teaches a flow control membrane composed of a first membrane (Fig. 5 element 124), an annular base membrane (Fig. 5 element 120) wherein an area of the base membrane substantially corresponds to that of the mounting portion and wherein the slit extend through the first membrane (Fig.5). Moorehead et al. does not specifically teach bonding the first membrane to the annular base membrane, further, with regards to claim 4, Moorehead et al. does not teach adhesive bonding

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between membranes. However, it would have been obvious to a person of ordinary skill in the art to adhesively bond and annular base (120) to a diaphragm (124) as such is an art recognized effective way of securing membrane layers together so as to maintain them in a desired position.

15. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) as applied to claims 1 and 2 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

Moorehead et al. differs from claims 5 and 6 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col.7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use membranes of a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to. Moorehead et al. differs from claim 7 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the

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art to apply the thickness range suggested in Fischer et al. to the membrane portions (Fig. 5 elements 122, 124) in Moorehead et al. as applied to claims 5 and 6. It directly follows that the thickness of the mounting portion will be between 1 and 6 times the thickness of the lumen occluding portion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Wachtel whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily Wachtel
Patent Examiner
Art unit 3709


SAM CHUAN YAO
PRIMARY EXAMINER